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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

08/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No. 10/566,226	Applicant(s) LAVI ET AL.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cameron (US Patent No. 5,342,320). Cameron discloses an injection device (Figs. 8-11) comprising: a housing (24) having a proximate end (near 40) and a distal end (near 128), the distal end having an opening therein; a cartridge barrel within the housing (18; please note that the claim language does not currently require that the cartridge barrel be a separate device/not connected to the housing), the cartridge barrel having proximate (near 126) and distal ends (near 102); a needle cannula fixed to the distal end of the cartridge barrel (20); a stopper within the cartridge barrel (76); a driver coupled to the stopper (12); a shield coupled to the housing (30/46/48) and slidable between a retracted (Figs. 8 and 9) and an extended position (Fig. 10); shield driver means activatable to urge the shield from the retracted position to the extended position (106); and sensor means (114) forming a portion of said driver (114 are connected to the driver via attachment area 110) and in slidable contact with an exterior surface of said cartridge barrel (114 slide along the exterior surface of 18), the sensor means arranged to detect an end profile of the barrel and automatically trigger

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activation of the shield driver means upon detection (Fig. 9 discloses that the end portions of 114 when they hit the end surface profile of the barrel at 102, they automatically disengage the shield portion 68 and allow the shield to be automatically activated and extended forward around the needles (Figs. 9-10).

In reference to claim 2, Cameron discloses that the shield driver means comprises a coil spring within which the cartridge barrel is located (106).

In reference to claim 3, Cameron discloses that the shield driver means comprises a release mechanism for fixing the spring relative to the driver in a compressed state, the release mechanism being actuatable by said sensor means to release the spring (Figs. 8-10).

In reference to claim 4, Cameron discloses that the driver is arranged to be manually pushed through the housing, the driver carrying the shield driver means to a shield activation point (Figs. 8-10).

In reference to claim 5, Cameron discloses that the coil spring is fixed at its proximal end to the driver, and the spring release mechanism fixes the spring to the driver at its distal end (Figs. 8-10).

In reference to claim 6, Cameron discloses that the shield driver means additionally provides a driving force for said driver (Figs. 8-10).

In reference to claim 7, Cameron discloses that the coil spring is fixed at its proximal end to the housing and the spring release mechanism fixes the spring to the driver at its distal end (Figs. 8-10).

In reference to claim 8, Cameron discloses that the sensor means comprises one or more deformable arms attached or formed integrally with the driver (114 are formed integrally with the driver).

In reference to claim 9, Cameron discloses that each arm is biased against the exterior surface of the cartridge barrel and arranged to follow the surface profile of the barrel (Figs. 8-10).

In reference to claim 10, Cameron discloses that the release mechanism comprises a catch provided on a radial outer surface of each deformable arm (Figs. 8-10).

In reference to claim 11, Cameron discloses that the driver and said sensor means are a single molded plastic element (Figs. 8-10).

In reference to claim 18, Cameron discloses that the driver is deformable during assembly (portion 76 is at least deformable and due to catches 120, these portions must also be deformable).

Claims 12, 13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Chevallier (US 2002/0193746). Chevallier discloses an injection device (Figs. 1-5 for example) comprising: a cartridge barrel (10), said barrel arranged to contain a stopper (not labeled with a reference number in Fig. 1) and a fluid therein and where said barrel has a second open end (near 20) and a second end having a radial flange adjacent to the second end (radial flange 20, also see Figs. 2-4); a needle

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cannula having a sharp distal end (14) and a second open end, the fluid being in communication with said needle second end; a housing (16) surrounding said barrel, said housing having a distal open end (near 16a) adjacent the needle and a proximate end having a flange receiving the radial flange of the barrel (proximal end has flange 24 as seen in Figs. 3 and 4); a shield releasably retained by the housing (19), said housing and said shield arranged in a sliding relationship with the shield positioned primarily within the housing until release (Figs. 1-5); a driver (12), said driver positioned partially within said housing, said driver equipped with at least one deformable side arm (portion 13 is being interpreted as the deformable side arm as this clearly is a side arm, and since the device is made of plastic, it has some degree of deformability. Furthermore, Applicant has not claimed what the side arm must deform in response to contacting) sensing the end of the barrel (Fig. 5 discloses that 13 contacts and senses the end of the barrel at 20 at which point the shield is automatically triggered. Please note that Applicant has not claimed which end of the barrel that the side arm must sense), said driver slidably located within said housing for moving the stopper forward (Figs. 1-5); and a biasing spring (34), said biasing spring further adapted to bias the shield to automatically cover the needle after said driver detects the end of the barrel (Fig. 5).

In reference to claim 13, Chevallier discloses that the biasing spring is carried by the driver and is released to bias the shield when the end of the barrel is reached (Figs. 1-5).

In reference to claim 15, Chevallier discloses that the housing and shield are equipped with latches (Figs. 1-5).

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In reference to claim 16, Chevallier discloses that the latches prevent the premature release of the shield (Figs. 1-5).

In reference to claim 17, Chevallier discloses that the latches retain the shield in a needle shielded position (Fig. 5 discloses that 30a retain the shield in the needle shielded position on flange 31a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chevallier (US 20020193746). Chevallier discloses the device substantially as claimed including one sensor element (13), however, Chevallier does not disclose two sensor elements. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Chevallier by adding a second sensing element, since it has

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been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767